UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	MDL Docket No. 2738
This Document Relates To All Cases	

DEFENDANTS JOHNSON & JOHNSON AND LLT MANAGEMENT, LLC'S MEMORANDUM OF LAW IN OPPOSITION TO THE PLAINTIFFS' STEERING COMMITTEE'S MOTIONS TO EXCLUDE THE OPINIONS OF DRS. JENNIFER PERMUTH, ANALISA DIFEO, AND JEFF BOYD

FAEGRE DRINKER BIDDLE & REATH LLP
A Delaware Limited Liability Partnership
600 Campus Drive
Florham Park, New Jersey 07932
(973) 549-7000

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
One Manhattan West
New York, NY 10001-8602
(212) 735-3000

Attorneys for Defendants Johnson & Johnson and LLT Management, LLC

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INTRODUCTION

In an apparent effort to try and salvage their own experts' wildly speculative biological plausibility opinions, plaintiffs seek to partially exclude the opinions of Drs. Permuth, DiFeo and Boyd, three highly qualified and widely published ovarian cancer researchers, who meticulously address the flaws in plaintiffs' experts' opinions.[1] Plaintiffs' motions fail for several reasons.[2]

As a threshold matter, plaintiffs' motions are based on a fundamental misunderstanding of the disparate roles of plaintiff and defense experts. Although Rule 702 applies to all expert testimony, "defendants' experts have a less demanding task, since they have no burden to produce models or methods of their own; they need only attack those of plaintiffs' experts." *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 285 (E.D.N.Y. 2007). With the correct standard in

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[1] Plaintiffs do not challenge the vast majority of Dr. Permuth's opinions, including her opinions on epidemiology. (*See* Rep. of Jennifer Permuth ("Permuth Rep."), May 28, 2024 (Permuth Br. Ex. 1).) They also do not challenge Dr. DiFeo's discussion of the flaws in various mechanistic articles, except to the extent she supposedly applied an overly stringent standard for what constitutes biological plausibility or allegedly failed to consider the component parts of talc. (*See* Rep. of Analisa DiFeo ("DiFeo Rep.") at 29-50, May 28, 2024 (DiFeo Br. Ex. 1).) They appear to challenge virtually all of the opinions in Dr. Boyd's supplemental 2023 report but not those in his original 2019 report.

[2] In the interests of judicial efficiency, this opposition responds to three motions: Pls.' Mot. to Exclude Ops. of Dr. Jennifer Permuth (ECF No. 33001), Pls.' Mot. to Exclude Ops. of Dr. Analisa DiFeo (ECF No. 33010) and Pls.' Mot. to Exclude Ops. of Dr. Jeff Boyd (ECF No. 33060).

mind, plaintiffs' arguments lack merit, for several reasons.

First, plaintiffs contend that it is too "speculative" for Drs. Permuth and DiFeo to testify that some genetic causes of ovarian cancer have not yet been discovered—and that genetics therefore cannot be ruled out as a cause of someone's ovarian cancer regardless of negative testing results.[3] This argument misstates the law because defense experts are allowed to offer alternative possible causes for a plaintiff's alleged injuries.

Second, plaintiffs argue that Drs. Permuth, DiFeo and Boyd fail to consider the individual constituents of talc (including alleged asbestos contamination) in critiquing plaintiffs' experts' opinions. This argument is procedurally improper because it regurgitates an argument that was rejected by Judge Wolfson without explaining why the Court's opinion was erroneous. It is also frivolous because these experts are responding to opinions by plaintiffs' experts who themselves focus on the product as it was sold, rather than its separate constituents. Notably, courts in similar cases have rejected plaintiffs' experts' attempts to analyze the individual components of a substance, rather than the substance as a whole, in determining whether it caused a particular injury.

Third, plaintiffs' argument that Drs. Permuth and DiFeo improperly held their experts to a standard of "certainty" with respect to the biological plausibility

[3] (*See* Permuth Br. at 4-10; DiFeo Br. at 3-7.)

factor of the Bradford Hill framework misapprehends the experts' opinions. The gist of those opinions is not that plaintiffs' experts must have absolute proof of biological plausibility; rather, it is that biological plausibility means something more than an untested hypothesis or a hypothesis that is unsupported by any reliable science.

Fourth, plaintiffs also seek to preclude Dr. Boyd from testifying about the limitations of the scientific literature on which plaintiffs' experts rely and the methodological flaws in certain in vitro studies, including heavily criticized papers by plaintiffs' former expert Ghassan Saed. Plaintiffs argue that Dr. Boyd is not qualified to criticize the literature and that the papers are immune from criticism once they are published (even though Dr. Saed's work, in particular, was rejected by multiple journals and described as "outrageous" by one peer reviewer). This argument, too, should be rejected. Dr. Boyd has decades of experience as a researcher, professor and peer reviewer, which more than suffices to evaluate the literature on which plaintiffs' experts rely. There is no legal support for the argument that an expert cannot criticize flaws in a study just because it has been peer-reviewed. Lastly, plaintiffs' halfhearted attacks on Dr. Boyd's qualifications and their attempt to contort his deposition testimony into a suggestion that he cherry-picked evidence should be rejected out of hand.

BACKGROUND

A. Drs. Permuth, DiFeo And Boyd

Dr. Permuth is a molecular epidemiologist at the H. Lee Moffitt Cancer Center and Research Institute and formerly was a genetic counselor for women diagnosed with ovarian cancer.[4] Dr. Permuth has authored or co-authored more than 100 peer-reviewed papers, reviews, book chapters, and other reports in the areas of genetics, epidemiology, molecular biology, and gynecologic and gastrointestinal oncology.[5]

Dr. DiFeo is a professor in the Department of Pathology and Obstetrics & Gynecology at the University of Michigan Medical School with 20 years of experience in biomedical research focused on ovarian cancer.[6] Dr. DiFeo is also Director of the Michigan Ovarian Cancer Science and Innovation Consortium and co-Principal Investigator of the gynecologic cancer tumor repository.[7] Dr. DiFeo is a reviewer associated with numerous journals and has published extensively on the subject of ovarian cancer.[8]

Dr. Boyd is the director of the Institute of Cancer Research at the Feinstein

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4 (Permuth Rep. at 4.)

5 (*Id.*)

6 (DiFeo Rep. at 2.)

7 (*Id.*)

8 (DiFeo Rep. App. A (DiFeo CV).)

Institutes for Medical Research, a professor in the Department of Obstetrics and Gynecology and Department of Pathology and Laboratory Medicine at the Zucker School of Medicine at Hofstra/Northwell and has over three decades of experience conducting cancer research.[9] Dr. Boyd has "authored or coauthored more than 200 articles, reviews, book chapters and editorials on the molecular and genetic bases of gynecologic or breast cancers," has been "invited to present more than 150 lectures on th[o]se topics throughout the world," and has "served as a peer reviewer in many capacities, including as a standing member of scientific review groups of the NIH, the Department of Defense cancer research program, and the American Cancer Society."[10] Dr. Boyd has also served on the editorial boards of a number of journals, including Gynecologic Oncology, the Journal of Clinical Oncology, Anticancer Research and the American Journal of Pathology.[11]

B. Genetic Mutations

Drs. Permuth and DiFeo opine that negative genetic testing does not preclude the possibility that a woman's ovarian cancer was caused by genetic mutations or Variants of Uncertain Significance ("VUSs").[12] VUSs are identified

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9 (*See* Boyd Rep. at 1.)

10 (*Id.* at 2; *see also* Boyd CV at 32 (Ex. 1 to Decl. of Jessica Davidson ("Davidson Decl.")).)

11 (Dep. of Jeff Boyd ("Boyd Dep.") 72:2-4, July 19, 2024 (Boyd Br. Ex. 2); *see also* Boyd CV at 7.)

12 (*See, e.g.*, Permuth Br. at 2-3; DiFeo Br. at 3-7.)

gene mutations whose relevance to clinical outcomes has not yet been determined; in other words, any specific VUS may or may not play a role in carcinogenesis. These experts also explain that not all genetic contributors to cancer have been identified and that scientists are continuing to discover mutations that cause ovarian cancer.[13] Dr. DiFeo specifically notes a study in which "VUS mutations were reclassified as pathogenic or likely pathogenic."[14] Similar reclassification is almost certain to continue happening in the future, as knowledge of cancer genetics advances.

Dr. Permuth identifies plaintiff-specific examples to illustrate this opinion, reviewing the VUSs that have been identified in Ms. Bondurant, Ms. Converse and Ms. Judkins, and explaining why there is reason to believe that they might have played a role in these women's ovarian cancer, even if their pathogenicity has not (yet) been fully established. That includes, for example, that particular "variants [identified for Ms. Converse] were later identified in [her] mother who had early-onset breast cancer," and that a VUS identified in Ms. Judkins "has been shown to be altered" in ovarian cancer patients.[15] Based on facts like these, she concludes that plaintiffs' experts are too quick to rule out the possibility of inherited

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[13] (DiFeo Rep. at 1, 13-14; Permuth Br. at 4-5; Dep. of Jennifer Permuth ("6/13/24 Permuth Dep.") 317:22-318:4, June 13, 2024 (Permuth Br. Ex. 2).)

[14] (DiFeo Rep. at 13.)

[15] (Permuth Rep. at 145-46.)

mutations as a cause of plaintiffs' cancers.

There is nothing controversial or novel about Drs. Permuth and DiFeo's opinions. Moreover, some of plaintiffs' experts expressed similar views. For example, plaintiffs' expert Dr. Clarke-Pearson is of the opinion that several unknown factors, likely including unknown mutations, contributed to Ms. Converse's ovarian cancer.[16] Likewise, Dr. Wolf testified that Ms. Gallardo may have had a mutation contributing to her ovarian cancer that was not identified in testing.[17]

Clinical evidence also supports Drs. Permuth and DiFeo's opinions. For example, Ms. Converse's treating physician concluded that despite Ms. Converse testing negative for known genetic mutations, she likely carries a gene for ovarian cancer that has not been identified given her family history.[18] Ms. Converse's

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[16] (Dep. of Daniel Clarke-Pearson ("8/27/2021 Clarke-Pearson Dep.") 450:21-25, 460:17-461:20, 584:17-25, 585:2-586:16, Aug. 27, 2021 (Ex. 2 to Davidson Decl.).) Similarly, Dr. Clarke-Pearson testified that there are unknown factors that caused Ms. Newsome's ovarian cancer. (8/27/2021 Clarke-Pearson Dep. 584:17-25, 585:2-586:16.) And Dr. Clarke-Pearson also testified that the largest percentage of factors causing ovarian cancer have yet to be discovered. (8/27/2021 Clarke-Pearson Dep. 472:3-474:11.)

[17] (Dep. of Judith Wolf ("4/25/24 Wolf Dep.") 35:25-36:17, 36:18-37:4, 39:7-40:13, Apr. 25, 2024 (Ex. 3 to Davidson Decl.).)

[18] (CONVERSE_HILARY_YALENEWHAVENHOSPITAL_00345 at 347 (Ex. 4 to Davidson Decl.); Dep. of Daniel Clarke-Pearson ("8/26/2021 Clarke-Pearson Dep.") 294:21-295:12, Aug. 26, 2021 (Ex. 5 to Davidson Decl.) (acknowledging that this is possible), 347:11-349:23.)

medical records also state that notwithstanding her genetic testing, "Genetics team believes she has a mutation that has not been discovered yet" relating to ovarian cancer.[19] Ms. Converse's treating physician, Dr. Schwartz, confirmed as much:

> Q: Dr. Schwartz, is it fair to say that Ms. Converse's family history is significant for cancer risk, including ovarian cancer risk?
> A: It would appear to be so, yes.
> Q: Is it fair to say that Ms. Converse's healthcare providers, including yourself, have concern that there may be a genetic mutation or an unidentified syndrome contributing to her cancer risk, including her ovarian cancer risk?
> A: Yes.[20]

In fact, based on the possibility that she has an unidentified gene that increases her risk of ovarian cancer, Ms. Converse's physicians are recommending that Ms. Converse's daughter be followed and considered for prophylactic ovary removal.[21]

C. Biological Plausibility

Drs. Permuth, DiFeo and Boyd rebut plaintiffs' experts' opinions on biological plausibility, explaining that their theories are mere hypotheses and that the available mechanistic evidence does not support the conclusion that talcum powder can cause ovarian cancer.[22] In forming their opinions, these experts

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[19] (CONVERSE_HILARY_PROHEALTHPHYSICIANSOFHAMDEN_00069 at 69 (Ex. 6 to Davidson Decl.).)

[20] (Dep. of Peter Schwartz ("Schwartz Dep.") 52:20-53:5, Jan. 28, 2021 (Ex. 7 to Davidson Decl.) (objection omitted).)

[21] (8/26/2021 Clarke-Pearson Dep. 359:13-362:12; CONVERSE_HlLARY_DRPETERSCHWARTZ_00125 at 128 (Ex. 8 to Davidson Decl.).)

[22] (*See infra* at 26-31.)

reviewed the same talc literature and studies relied upon by plaintiffs' experts, which generally consider cosmetic talc as a whole, rather than its specific components. While some of plaintiffs' expert reports include references to the alleged presence of asbestos, fibrous talc, heavy metals, and/or fragrances, which they claim are present in talc and may contribute to its carcinogenicity, their mechanistic opinions—like those of defendants' experts—focus on studies involving cosmetic talcum powder as a whole, not its specific alleged components.

D. Dr. Saed's Experiments And Dr. Boyd's Qualifications To Address Them

Dr. Saed is a former plaintiffs' expert, whose experiments involving talc have been heavily criticized in the scientific literature. When Dr. Saed was offered as an expert, Judge Wolfson prohibited him from linking talc to ovarian cancer, but permitted him to opine that talc caused oxidative stress in his in vitro experiments. *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Litig.*, 509 F. Supp. 3d 116, 136-40, 175 (D.N.J. 2020). Plaintiffs' current experts use Dr. Saed's research for exactly what Judge Wolfson held it cannot show: that talc causes cancer.[23]

[23] (*See* 3d Am. Rep. of Rebecca Smith-Bindman ("Smith-Bindman 3d Am. Rep.") at 15, May 28, 2024 (Ex. 9 to Davidson Decl.) ("These findings . . . provide a molecular mechanism to previous reports linking genital [talc] use to increased ovarian cancer risk.") (quoting Fletcher 2019); 3d Am. Rep. of Anne McTiernan ("McTiernan 3d Am. Rep.") at 91, May 28, 2024 (Ex. 10 to Davidson Decl.)

(cont'd)

Dr. Boyd opines on numerous flaws in the design, methodology and interpretations of Dr. Saed's studies.[24] Dr. Boyd is well qualified to render these opinions given his decades of experience as a cancer researcher, professor and peer reviewer.[25]

ARGUMENT

Although Rule 702 applies to both plaintiff and defense experts, "defendants' experts have a less demanding task, since they have no burden to produce models or methods of their own; they need only attack those of plaintiffs' experts." *In re Zyprexa*, 489 F. Supp. 2d at 285. Consistent with this lesser obligation, "a defense expert is not required to put forth a definitive opinion on causation in order to be helpful to the trier of fact." *OmniSource Corp. v. Heat Wave Metal Processing, Inc.*, No. 13-772, 2015 WL 3452918, at *6 (E.D.N.C.

("providing a molecular basis for epidemiologic studies demonstrating an increased risk of ovarian cancer"); Suppl. Rep. of Sonal Singh ("Singh Suppl. Rep.") at 14-15, Nov. 15, 2023 (Ex. 11 to Davidson Decl.) (treating Fletcher among studies "which have provided further evidence in support of a causal association"); *see also* 2d Am. Rep. of Shawn Levy ("Levy 2d Am. Rep.") at 16, May 28, 2024 (DiFeo Br. Ex. 6) (citing Fletcher's CA-125 findings, which Judge Wolfson found are "not a reliable measure of the risk of ovarian cancer resulting from talc use," *In re Johnson & Johnson*, 509 F. Supp. 3d at 139); 3d Am. Rep. of Judith Wolf ("Wolf 3d Am. Rep.") at 17, May 28, 2024 (DiFeo Br. Ex. 15) (similar).)

[24] (Boyd Br. at 17-20.)

[25] (*See* Boyd Rep. at 1; *id.* at 2; *see also* Boyd CV at 32.) Plaintiffs do not challenge similar opinions offered by Dr. DiFeo, who also opines on the flaws in Dr. Saed's research.

May 29, 2015); *see also Shadrick v. S. Health Partners, Inc.*, No. 11-00033, 2016 WL 4555611, at *10 (W.D. Ky. Aug. 31, 2016) (noting that "[i]n contrast, defendants are not required to 'disprove' causation" and "must only produce 'credible evidence which tends to discredit or rebut the plaintiff's evidence' so as to 'convince the trier of fact that the alleged negligence was not the legal cause of the injury") (citations omitted). Rather, it is "entirely appropriate" for defendants' experts to offer what are, "essentially, critiques of [p]laintiffs' experts' evidence, methodologies, and conclusions." *In re Abilify (Aripiprazole) Prods. Liab. Litig.*, 299 F. Supp. 3d 1291, 1368 (N.D. Fla. 2018); *see also, e.g.*, *Feliciano v. Corelogic Saferent, LLC*, No. 17-5507, 2020 U.S. Dist. LEXIS 199069, at *8 (S.D.N.Y. June 11, 2020) (defense expert can simply "pok[e] holes in [other side's] argument"); *Washington v. Kellwood Co.*, 105 F. Supp. 3d 293, 326 (S.D.N.Y. 2015) ("Defendant states—and we concur—that 'case law supports . . . that it is perfectly acceptable for an expert to critique another expert's opinion on damages without offering his or her independent opinion.'") (citation omitted); *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 786 (3d Cir. 1996) ("the test is different" for defense experts because the burden of proving causation is one that "the defense d[oes] not bear"). It is thus sufficient, for example, for a defense expert to "point[] to the absence of convincing studies or the weaknesses of studies on which [p]laintiffs rely, and evaluat[e] them in light of their . . . experience, training and research."

See, e.g., *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 418-19 (S.D.N.Y. 2016) (rejecting the "general thrust of [p]laintiffs' arguments," which is that the defense experts have not "pointed to studies ruling out the possibility of secondary perforation"). In addition, "a defendant may offer evidence of potential alternative causes of a disease or injury without needing to prove those alternative-cause theories with certainty or probability." *Nat'l Union Fire Ins. Co. of Pittsburgh PA v. SPX Flow US, LLC*, No. 18-80332, 2019 WL 1227987, at *4 (S.D. Fla. Mar. 14, 2019) (citation omitted).

When defendants' experts' opinions are evaluated under the proper standard, all of plaintiffs' arguments fail.

I. DRS. PERMUTH AND DIFEO'S OPINIONS ON GENETICS ARE ADMISSIBLE.

Plaintiffs seek to prevent Drs. Permuth and DiFeo from explaining to jurors that because many genetic causes of ovarian cancer remain to be discovered, negative genetic testing does not mean that one can rule out genetics as a cause of a woman's ovarian cancer. (*See* Permuth Br. at 4-10; DiFeo Br. at 3-7.) According to plaintiffs, such opinions are "speculative" and "unfounded."

Plaintiffs' arguments fail for several reasons.

First, the experts' opinions are well grounded in their experience and in the relevant science.

Dr. DiFeo has a wealth of experience in cancer genetics. She has a Ph.D.

in Cancer Genetics from Mount Sinai School of Medicine, and she oversees "a translational ovarian cancer research laboratory," which "spans the continuum of translational research beginning with an in-depth analysis of patient tumors and progressing to a functional assessment of key genetic drivers of ovarian cancer progression."[26] Based on this experience (and her daily work in ovarian cancer genetics), she explains in her report that "new genes" that contribute to the development of ovarian cancer "continue to be identified" and provides several examples of genes that are known to "predispose a woman to developing ovarian cancer," even though the "exact mutations . . . that cause cancer" are unknown.[27] She further explains that some identified VUS mutations, as well as mutations thought to be non-pathogenic, were later reclassified as cancer-causing.

Dr. Permuth similarly relies on her broad experience in genetic research and counseling, as well as her comprehensive review of each plaintiff's genetic testing. Plaintiffs take issue with Dr. Permuth highlighting plaintiff Bondurant's SDHA germline mutation as a "possib[le]" cause of her ovarian cancer,[28] but Dr. Permuth explains that "SDHA mutations have actually been reported in a woman with clear cell ovarian cancer and endometriosis," noting that this "gene has definitely been

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26 (DiFeo Rep. at 1, 13-14.)

27 (*Id.*)

28 (Permuth Br. at 4-5.)

implicated in ovarian tumorigenesis, so there is plausibility for how this mutation could contribute to" Ms. Bondurant's ovarian cancer.[29] Similarly, with respect to plaintiff Converse, Dr. Permuth notes that "[b]oth of her [VUSs] were later identified in her mother who had early-onset breast cancer" and that the pathogenicity of those variants remains "unclear."[30] The same is true with respect to the PTEN mutation discovered in plaintiff Judkins, which Dr. Permuth explains "has been shown to be altered in the germline . . . in a study of patients with breast cancer and OvCa,"[31] and with the MUTYH gene mutation in plaintiff Newsome, since these mutations have similarly "been observed in the germline of women with OvCa."[32] In short, both experts have good grounds for their opinions that other genetic causes may be "possible" causes of each plaintiffs' ovarian cancer.

Plaintiffs' arguments are also undermined by the fact that some of their own experts have expressed similar opinions to those of Drs. Permuth and DiFeo. Specifically, several of plaintiffs' experts agreed at their depositions that only some of the causes of ovarian cancer are presently known[33] and that many risk

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29 (6/13/24 Permuth Dep. 317:22-318:4.)

30 (Permuth Rep. at 145-46.)

31 (*Id.* at 146-47.)

32 (*Id.* at 147.)

33 (Dep. of Judith Wolf ("9/13/21 Wolf Dep.") 401:15-402:16, Sept. 13, 2021 (Ex. 12 to Davidson Decl.); Dep. of Judith Wolf ("9/14/21 Wolf Dep.") 534:5-9, 547:24-548:11, Sept. 14, 2021 (Ex. 13 to Davidson Decl.); Dep. of Shawn Levy

(cont'd)

factors or causes are yet to be discovered, including genetics.[34] For example, plaintiffs' expert Dr. Clarke-Pearson is of the opinion that an unknown number of unknown factors, likely unknown genetic mutations, contributed to Ms. Converse's ovarian cancer.[35] Likewise, Dr. Wolf testified that Ms. Gallardo may have had a mutation contributing to her ovarian cancer that was not identified in testing.[36]

The experts' opinions are also supported by clinical evidence. For example, Ms. Converse's treating physician concluded that despite Ms. Converse testing negative for known genetic mutations, given her family history, it is likely that she carries a gene for ovarian cancer that has not been identified.[37] As noted above,

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105:18-107:14, 107:15-108:3, Jan. 11, 2019 (Ex. 14 to Davidson Decl.); Dep. of Jack Siemiatycki ("1/31/19 Siemiatycki Dep.") 173:6-9, Jan. 31, 2019 (Ex. 15 to Davidson Decl.) (agreeing that "all of the factors that might make someone susceptible to developing ovarian cancer are not yet known"); Dep. of Sarah Kane ("Kane Dep.") 144:1-3, 144:25-145:1, Jan. 25, 2019 (Ex. 16 to Davidson Decl.); 8/26/2021 Clarke-Pearson Dep. 283:20-284:20, 294:21-295:12, 337:1-4 (testifying that "[she] can't rule out an unknown cause of Ms. Converse's ovarian cancer"), 347:11-349:23; 8/27/2021 Clarke-Pearson Dep. 452:25-453:4.) And Dr. Clarke-Pearson also testified that the largest percentage of factors causing ovarian cancer have yet to be discovered. (8/27/2021 Clarke-Pearson Dep. 472:3-474:11.)

[34] (8/27/2021 Clarke-Pearson Dep. 472:3-474:11.)

[35] (8/27/2021 Clarke-Pearson Dep. 450:21-25, 460:17-461:20, 584:17-25, 585:2-586:16.) Similarly, Dr. Clarke-Pearson testified that there are unknown factors that caused Ms. Newsome's ovarian cancer. (8/27/2021 Clarke-Pearson Dep. 584:17-25, 585:2-586:16.)

[36] (4/25/24 Wolf Dep. 35:25-36:17, 36:18-37:4, 39:7-40:13.)

[37] (CONVERSE_HILARY_YALENEWHAVENHOSPITAL_00345 at 347; 8/26/2021 Clarke-Pearson Dep. 294:21-295:12 (acknowledging that this is possible), 347:11-349:23.)

Ms. Converse's medical records state that notwithstanding extensive genetic testing, "Genetics team believes she has a mutation that has not been discovered yet" relating to ovarian cancer.[38] In addition, based on her potential to have an unidentified gene for ovarian cancer, her physicians are recommending that Ms. Converse' daughter be followed and considered for prophylactic ovary removal.[39]

Second, while plaintiffs suggest that an expert cannot merely testify to "possible" causes, their arguments confuse the roles of plaintiff and defense experts. As explained above, because it is the plaintiff who "bears the ultimate burden of proof, a defense expert is not required to put forth a definitive opinion on causation in order to be helpful to the trier of fact." *OmniSource Corp.*, 2015 WL 3452918, at *6. Thus, "[d]efense experts are not bound by the 'probability' standard and may introduce testimony couched only in terms of 'possibility.'" *Shadrick*, 2016 WL 4555611, at *10 (citation omitted). That is precisely what defense experts seek to do here: to address the possibility that certain plaintiffs may have genetic causes for their ovarian cancer. Because plaintiffs cite cases involving plaintiffs' experts and plaintiffs' burden of proof, their cases are

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[38] (CONVERSE_HILARY_PROHEALTHPHYSICIANSOFHAMDEN_00069 at 69; *see also* Schwartz Dep. 52:20-53:5 (Dr. Schwartz confirming his "concern that there may be a genetic mutation or an unidentified syndrome contributing to [plaintiff Converse's] cancer risk").)

[39] (8/26/2021 Clarke-Pearson Dep. 359:13-362:12; CONVERSE_HlLARY_DRPETERSCHWARTZ_00125.)

inapposite.

For example, plaintiffs cite *In re Bausch & Lomb Inc. Contacts Lens Solution Products Liability Litigation* for the proposition that "speculation about future links between [a product] and [a disease] is not sufficient" to satisfy Rule 702,[40] but plaintiffs omit the beginning and end of that sentence, which show its inapplicability to the circumstances here. Read in full, the sentence stated: "***Plaintiff Hobbs'*** speculation about future links between [a product] and [a disease] is not sufficient to survive a ***motion for summary judgment*** ripe for ruling today." 693 F. Supp. 2d 515, 520 (D.S.C. 2010) (emphasis added).

In *Bausch*, the court had already excluded the plaintiffs' "only general causation expert," meaning their claims could "[]not survive" summary judgment. *Id.* at 518. In a last-ditch effort to save his claims, one plaintiff argued that because it was "possible that a provable link to non-fusarium infections" and the product would "be established in the future," any dismissal should be without prejudice. *Id.* at 520. The court rejected that argument, holding that a ***plaintiff's*** speculation alone is not enough to survive summary judgment. *Id.* *Bausch* says nothing about the standard of certainty that governs ***defense expert*** testimony—only that a plaintiff, who has the burden of proof, may not base her claims on some speculative future link.

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40 (Permuth Br. at 7-8; DiFeo Br. at 4-5.)

Henricksen v. Conoco Phillips Co. is uninformative for much the same reason.[41] There, the court did not address the standard applicable to defense experts rebutting plaintiffs' experts' opinions on causation; rather, it excluded a ***plaintiff's*** general and specific causation expert who sought to opine that exposure to gasoline caused his disease. *Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1168-69 (E.D. Wash. 2009).

In sum, Drs. Permuth and DiFeo, as defense experts, need not say that genetics are a likely cause of any plaintiff's cancer. Moreover, their genetics opinions are consistent with the science, plaintiffs' own experts' admissions and clinical evidence. Accordingly, plaintiffs' arguments lack merit and should be dismissed.

II. THE THREE EXPERTS' BIOLOGICAL PLAUSIBILITY OPINIONS ARE ADMISSIBLE.

A. Defendants' Experts Properly Consider Talcum Powder As A Whole.

Even though their own experts largely attack talcum powder as one product, plaintiffs criticize defendants' experts for failing to address "the individual ingredients in talcum powder, including whether asbestos, fibrous talc, platy talc, heavy metals, and fragrances can cause or increase the risk of ovarian cancer."[42]

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41 (Permuth Br. at 7; DiFeo Br. at 4.)

42 (Permuth Br. at 2-3; DiFeo Br. at 1 ("[S]he fails to consider the actual constituents of talcum powder."); Boyd Br. at 11-12 (similar).)

This argument fails for multiple reasons.

First, plaintiffs' argument violates the Court's April 30, 2024, which states as follows:

> if Chief Judge Wolfson entered a decision on an issue and either party wishes to challenge that decision, briefing on the upcoming in limine motions should set forth Chief Judge Wolfson's previous decision and on what basis the party contends that decision should be reconsidered. In other words, the briefing should identify either: (1) that Chief Judge Wolfson's previous Opinion demonstrably fails to adhere to Rule 702 as clarified by the 2023 amendments; or (2) new science is shown to directly contradict or challenge Chief Judge Wolfson's previous findings.

(ECF No. 32122 at 6.) In the first round of *Daubert* briefing, plaintiffs argued to Judge Wolfson that one of defendants' experts' opinions was "unreliable because the expert [Dr. Ben Neel] did not consider the components of talc," faulting him "for not analyzing whether talc contains known carcinogens, such as asbestos or other heavy metals." *In re Johnson & Johnson*, 509 F. Supp. 3d at 196-97. Judge Wolfson rejected plaintiffs' argument, holding that there is no requirement for defendants' expert to "opine as to the components of talc" because he "has been proffered as an expert to rebut the methodology" of plaintiffs' expert who opines that "talc *itself*" can cause ovarian cancer. *Id.* at 197.[43] Plaintiffs do not even acknowledge that ruling, let alone explain why it should be reconsidered.

[43] At the beginning of her opinion, Chief Judge Wolfson explained that "the reasoning in this Court's Opinion, applies with equal force to the remainder of the pending *Daubert* motions." *In re Johnson & Johnson*, 509 F. Supp. 3d at 128-29.

Second, putting aside the procedural flaw in plaintiffs' argument, it should be rejected for all the same reasons Judge Wolfson rejected it the first time. Defendants' experts are responding to opinions and studies that address cosmetic talc as it was sold, with all its constituents. Dr. Permuth has explained repeatedly in her depositions that her opinion is that there is no evidence that talcum powder ***as a whole***—whatever comprises it—causes ovarian cancer.[44] In other words, the studies she relied on necessarily considered all the components of cosmetic talcum powder. Plaintiffs concede that Drs. DiFeo and Boyd "opine[] that cosmetic talc, ***regardless of its exact constituents***, does not cause or contribute to the development of ovarian cancer, and that there is no evidence talcum powder causes

[44] (*See, e.g.*, 6/13/24 Permuth Dep. 42:14-43:6 (noting that she considered talcum powder "as a whole," including the potential that it contains asbestos); 200:8-11 ("I looked at the bulk of the data and the associations of talc as a substance and not constituents and ovarian cancer."); 201:15-19 ("I considered the substance as a whole in their associations with ovarian cancer risk, so I'm not going to be talking about how this one fiber type differs from another . . . ."); 303:18-304:15 ("I don't believe talc as a whole causes ovarian cancer."); Dep. of Jennifer Permuth 38:10-13, *Matthey v. Johnson & Johnson*, No. 2018-CA-4809-NC (Fla. Cir. Ct. Nov. 24, 2020) (Ex. 17 to Davidson Decl.) ("I think of talc as an entity."); 39:13-16 ("As I said, I looked at talc as a whole."); 39:24-40:8 ("Again, I know I sound like a robot here, but I evaluated talc and what was reported to be talc."); 40:14-18 ("Again, I looked at talc as a whole"); 55:7-15 ("I guess I would go back to what I said earlier, I considered the powder as a whole, as an entity, and its association with the diseases of interest, ovarian cancer."); 142:13-15 ("[W]hen one is exposed to talc, it doesn't appear to be carcinogenic to the ovaries.").)

malignant transformation of epithelial cells."[45] That makes perfect sense. Studies of talc (whether epidemiological, animal, or in vitro) necessarily account for its constituent parts, including, to the extent they actually exist, trace heavy metal or trace asbestos impurities.

This is all the more true because as part of assessing the scientific evidence and methodologies and conclusions of plaintiffs' experts, defendants' experts examined the same talc studies that plaintiffs' experts cited to support their opinions.[46] Plaintiffs, of course, have never suggested that the literature or studies upon which their experts relied were irrelevant because these studies analyzed talc

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[45] (DiFeo Br. at 8 (emphasis added); *see also* DiFeo Rep. at 6 ("I conclude that cosmetic talc, regardless of its exact constituents or alleged contaminants, does not cause or contribute to the development of ovarian cancer."); Boyd Br. at 12; *see also* Boyd Dep. 200:2-16 ("I base my opinion on whatever is in the bottle labeled 'Johnson's Baby Powder.'").)

[46] (*See, e.g.*, Permuth Rep. at 123 (assessing study by Poole and colleagues that "Plaintiffs' experts have recently cited"), 135 ("reviewing the causation analyses set forth in reports of plaintiffs' experts cited in the Health Canada assessment"), 137-38 (discussing Dr. Smith-Bindman's citations to O'Brien and Woollen studies), 138 (discussing sets of studies cited by Dr. Smith-Bindman), 141 (assessing Dr. Siemiatycki citations to studies by Terry, Schildkraut, and Woollen), 142-43 (assessing studies by Saed and Brieger cited by Dr. Levy as "support for his hypothesis that talc induces inflammation and subsequent OvCa"); DiFeo Rep. at 6 ("The studies on which plaintiffs' experts rely have been performed on flawed cell lines, use physiologically irrelevant concentrations of talc, and, in any event, do not demonstrate neoplastic transformation."); *see, e.g.*, Boyd Rep. at 3 ("Generally, the conclusions of Dr. Saed's studies are dependent upon multiple layers of speculation. These studies are replete with multiple flaws in study design, execution, and interpretation that completely undermine his stated conclusions.").)

as a whole rather than the individual constituents.

Plaintiffs' argument is particularly confusing because many of plaintiffs' experts similarly express opinions about talc a***s a whole*** (and have sought to publish articles in the scientific literature to support plaintiffs' claims about talc as a whole). To be sure, certain of plaintiffs' experts' reports mention in passing that various constituents of talc may be carcinogenic, toxic or inflammatory (opinions that are all speculative and unreliable for the reasons set forth in defendants' pending Rule 702 motions).[47] But when asked whether they performed any scientific analysis to support their positions on these constituents, they testified over and over that they did not perform such analyses because they were analyzing

[47] (*See, e.g.*, 3d Am. Rep. of Jack Siemiatycki at 1 n.1, 27, 71, May 27, 2024 (Ex. 18 to Davidson Decl.) (expressing opinion based on assumption that commercially available talc contains asbestos, fibrous talc, heavy metals, and fragrances); McTiernan 3d Am. Rep. at 84 ("It is important to note that [commercially-available talc] is not asbestos-free. Talcum powder products contain other, potentially carcinogenic substances; of greatest concern is the presence of asbestos in talc, and the presence of talc with asbestiform fibers (fibrous talc), in these products."); Expert Rep. of Arch Carson at 4, Nov. 16, 2018 (Ex. 19 to Davidson Decl.) ("Talc deposits are often intermingled with asbestos and vice versa."); 3d Am. Rep. of Daniel Clarke-Pearson at 7-8, May 28, 2024 (DiFeo Br. Ex. 17) ("Talcum powder also contains other carcinogens including asbestos, talc containing asbestiform fibers (fibrous talc), heavy metals such as nickel, chromium and cobalt (possible 2b), and other inflammatory agents, toxins, and carcinogens contained in the fragrance chemicals in talcum powder."); Rep. of Judith Zelikoff at 7, Nov. 16, 2018 (Ex. 20 to Davidson Decl.) ("Defendants have claimed that asbestos has been 'eliminated' from cosmetic talc products. However, there is substantial evidence that talcum powder products still contain asbestos . . . .") (footnote omitted).)

the properties of talc as a whole. To quote plaintiffs' expert Dr. Clarke-Pearson:

> I don't know what it is about talcum powder that caused her ovarian cancer. Could it be heavy metals? Could it be fragrances? Could it be asbestos that we're not aware of? I would just say that Johnson's Baby Powder causes ovarian cancer. Whatever the constituents are, I don't think anybody can pin that down.[48]

Dr. Cote similarly testified that she did not perform a scientific or comprehensive review of the components of talc because her opinion is about "talc as a whole. It was not the components. It was whatever was in the bottles or containers of talc that the women were using."[49] And Dr. Moorman echoed this sentiment, explaining "I -- I am not making, really, any assumptions that these [constituents] are in the products. My -- you know, my focus on the epidemiologic data is based on the use of the talc products, whatever is contained in them."[50] At least six other plaintiffs' experts offered similar testimony—i.e., that they analyzed the purported connection between ovarian cancer and talc as a whole, regardless of the constituents.[51]

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[48] (8/26/2021 Clarke-Pearson Dep. 292:23-294:13.)

[49] (Dep. of Michele Cote 110:25-113:2, Mar. 21, 2024 (Ex. 21 to Davidson Decl.).)

[50] (Dep. of Patricia Moorman 295:25-298:10, Jan. 25, 2019 (Ex. 22 to Davidson Decl.); *see also id.* 119:14-25, 125:2-126:6.)

[51] (*See, e.g.*, Dep. of Judith Wolf 110:16-111:9, 376:15-377:2, Jan. 7, 2019 (Ex. 23 to Davidson Decl.); 9/13/21 Wolf Dep. 410:6-17, 412:23-416:3; 9/14/21 Wolf Dep. 588:12-589:2; 4/25/24 Wolf Dep. 53:11-15 ("[Q.] For purposes of your opinion in this case, are you quantifying any affect that asbestos has separate from

(cont'd)

Moreover, Dr. Saed, whose studies are the cornerstone of plaintiffs' experts' biological plausibility opinions, expressly disclaimed any reliance on asbestos and heavy metals in connection with his conclusion that talc causes ovarian cancer:

> Q. Are your opinions in this case premised on talc containing asbestos?
> A. (Witness shakes head from side to side.) I don't know, no, my opinion has nothing to do with that.
> Q. Are your opinions in any way based on talc having heavy metals in them?
> A. No.[52]

Finally, courts around the country have rejected plaintiffs' experts' attempts to analyze the individual components of a substance, rather than the whole, in determining whether the substance caused a particular injury. *See In re Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F. Supp. 3d 1075, 1108 (S.D. Fla. 2022)

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talcum powder, the product itself? A. No. I mean, it's the entire product and asbestos is in that product."); Dep. of Shawn Levy 118:9-18, 121:16-122:11, 127:5-128:6, May 8, 2024 (Ex. 24 to Davidson Decl.) (testifying that his "opinions are -- were focusing on the totality of the product" and references to constituents were for "background"); Dep. of Jack Siemiatycki 55:20-56:7, Mar. 27, 2024 (Ex. 25 to Davidson Decl.); Dep. of Judith Zelikoff 270:1-272:4, 277:24-278:16, Jan. 21, 2019 (Ex. 26 to Davidson Decl.); Dep. of Rebecca Smith-Bindman 136:15-137:19, Feb. 7, 2019 (Ex. 27 to Davidson Decl.); Dep. of Laura Plunkett 272:24-273:6, Dec. 19, 2018 (Ex. 28 to Davidson Decl.) ("But on the issue of ovarian cancer, I'm looking at the data that's been collected on talc itself, which would be talc with the constituents that could include the metals."); Dep. of Laura Plunkett 182:23-25, Dec. 21, 2023 (Ex. 29 to Davidson Decl.) ("So the epidemiological literature related to perineal use of talc, it's talc with all the things in it."); Kane Dep. 133:23-135:2 ("what I am opining about is the ultimate product," not the constituents), 138:11-140:25, 288:16-23; 8/26/2021 Clarke-Pearson Dep. 336:9-24.)

[52] (Dep. of Ghassan Saed 264:2-8, Jan. 23, 2019 (Ex. 30 to Davidson Decl.).)

(holding that it was correct to "fram[e] the general causation question ***on the product the [p]laintiffs consumed***, ranitidine, in lieu of the mechanistic theory by which the [p]laintiffs seek to prove their case, [the ingredient] NDMA") (emphasis added); *Henricksen*, 605 F. Supp. 2d at 1156; *Burst v. Shell Oil Co.*, No. 14-109, 2015 WL 3755953, at *9 (E.D. La. June 16, 2015), *aff'd*, 650 F. App'x 170 (5th Cir. 2016). For example, in *Henricksen* (one of plaintiffs' own cited authorities), the plaintiff claimed that he became ill from exposure to the defendant's gasoline because benzene is a component of the gasoline. The court rejected the plaintiff's contention that his experts could simply rely on studies showing that benzene causes illnesses. According to the court, "[t]his is a products liability action and [d]efendant's product is gasoline. It is undisputed that Henricksen's exposure was to the mixture gasoline not simply the substance benzene. . . . [T]he court cannot simply presume that the qualitative toxic and carcinogenic effects of benzene from *any source* are the same." *Henricksen*, 605 F. Supp. 2d at 1156. Similarly, the *Burst* court rejected an expert's attempt to analyze benzene separately from gasoline because "[t]he question here . . . is whether exposure to gasoline containing benzene can cause AML, not whether exposure to benzene generally can cause AML." *Burst*, 2015 WL 3755953, at *9. These cases hold that an expert ***must*** consider an allegedly harmful product as a whole rather than focus myopically on its component parts. It follows perforce than an expert is, at

minimum, permitted to do so.

In short, plaintiffs apparently are taking the position that defendants' experts should not have analyzed cosmetic talc as a whole, even though this litigation is about cosmetic talc, all of the epidemiology they rely on involves cosmetic talc and their own experts largely (if not exclusively) focused their opinions on cosmetic talc. This argument is both procedurally improper and substantively frivolous. Accordingly, it should be rejected.

B. Drs. Permuth And Difeo Properly Critique Plaintiffs' Experts' Biological Plausibility Opinions As Unsupported By Reliable Scientific Evidence.

Plaintiffs also argue that defendants' experts' opinions regarding biological plausibility are unreliable because they are based "on an incorrect standard requiring perfected 'proof' of migration, inflammation, and/or malignant transformation, rather than a plausible mechanism."[53] This argument distorts defendants' experts' opinions. Defendants' experts do not demand absolute proof. Rather, they have opined that this Bradford Hill factor is not satisfied because plaintiffs' proposed biological mechanisms are merely hypotheses, unsupported by reliable mechanistic evidence.

The biological plausibility factor requires more than an "untested

[53] (DiFeo Br. at 12; *see also* Permuth Br. at 14 ("Dr. Permuth applied the wrong standard to biological plausibility.").)

mechanism hypothesis," even one that might be "possibly true." *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig.*, 341 F. Supp. 3d 213, 303, 305 (S.D.N.Y. 2018) (excluding mechanism opinion because it was "beset by analytic and evidentiary gaps at multiple steps"); *see, e.g.*, *In re Accutane Prods. Liab.*, 511 F. Supp. 2d 1288, 1295-96 (M.D. Fla. 2007) (excluding "unproven hypothesis; "[W]hile [expert's] biological theory may be exactly right, at this point it is merely plausible, not proven, and biological possibility is not proof of causation."); *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 534, 561-62 (W.D. Pa. 2003) ("While *Daubert* does not require absolute precision in identifying the medical mechanism of injury, there still must be 'sufficiently compelling proof that the agent must have caused the damages somehow.'") (citation omitted). Thus, while absolute certainty is not required, something more than guesswork is needed.[54]

[54] Plaintiffs' authority does not support a contrary conclusion. *In re Fosamax Products Liability Litigation* involved a biological mechanism that was shown to take place in rats and dogs and was so widely accepted that "[n]early every report and review of [the condition] point[ed] to" the proposed mechanism "as a likely mechanism." 645 F. Supp. 2d 164, 182 (S.D.N.Y. 2009) (citation omitted) (cited in DiFeo Br. at 16 n.49; Permuth Br. at 15 n.45). No comparable evidence exists here. *In re Pfizer Inc. Securities Litigation* likewise involved a theory that had "been deemed plausible and credible in the relevant medical literature." No. 04-9866, 2010 WL 1047618, at *6 (S.D.N.Y. Mar. 22, 2010), *as amended* (Mar. 29, 2010) (cited in DiFeo Br. at 17 n.49; Permuth Br. at 15 n.45). And *Milward v. Acuity Specialty Products Group, Inc.*, 639 F.3d 11 (1st Cir. 2011) (cited in DiFeo Br. at 8; Permuth Br. at 11), was described by the chair of the subcommittee that drafted the recent Rule 702 amendments as a "prime example of the problem" that the amendments were intended to solve, Thomas D. Schroeder, *Toward a More*

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Plaintiffs' attacks on defendants' experts attempt to obscure the fact that all their experts can offer is guesswork. In reality, it is plaintiffs' experts whose opinions must be excluded, not defendants'.

For example, plaintiffs argue that Dr. Permuth applied the wrong standard of biological plausibility because she testified that she "can't find anything that proves that hypothesis [i.e., that talc particles can migrate from the external perineum to the ovaries] . . . . There's nothing out there."[55] But Dr. Permuth was not using the word "prove" in any absolute sense. Nor was she suggesting that plaintiffs needed to offer proof of a certain biological mechanism by which talc can cause ovarian cancer. Rather, it is clear from the broader context of her testimony that she simply meant, based on her review of the literature, that there is no evidence supporting the hypothesis that talc can migrate from the external perineum to the ovaries.[56] She did not testify or imply that plaintiffs' experts

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Transparent Approach to Considering the Admission of Expert Testimony, 95 Notre Dame L. Rev. 2039, 2043-44 (2020).

[55] (Permuth Br. at 14 (quoting 6/13/24 Permuth Dep. 176:16-177:7).)

[56] (6/13/24 Permuth Dep. 176:8-177:7 (testifying: "I can't find anything that proves -- I can't find anything that proves that hypothesis, if that's what you're asking. There is nothing out there.").) It also bears noting that the portion of testimony plaintiffs cite was offered in response to a nearly unintelligible question from plaintiffs' counsel (which defendants' counsel objected to on that basis): "And I asked you for -- Cramer does purport that but I don't believe that there's any epidemiological study that also purports that that would cite Cramer as to the explanation." (*Id.* 176:20-23.) It is not reasonable to interpret Dr. Permuth's

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needed to prove biological plausibility with certainty to satisfy Bradford Hill.

Plaintiffs' effort to show that Dr. DiFeo has equated plausibility with absolute proof fails for similar reasons. Plaintiffs claim that Dr. DiFeo applied a standard of plausibility requiring "perfected 'proof' of migration, inflammation, and/or malignant transformation, rather than a plausible mechanism."[57] But Dr. DiFeo's report and testimony show that Dr. DiFeo (like Dr. Permuth) was describing biological plausibility in terms of the lack of any supportive evidence rather than definitive proof. For example, Dr. DiFeo explained that "to date, ***there have been no studies*** that have demonstrated that cosmetic talc induces neoplastic transformation."[58] Similarly, she opined that "***there is no evidence*** that inflammation precedes HGSC and ***there is no evidence*** of an association between chronic inflammation and the occurrence of the precursor's lesions of HGSC."[59]

In other portions of the testimony cited by plaintiffs, Dr. DiFeo offered her interpretation of other researchers' findings with respect to biological plausibility. For instance, she testified that O'Brien concluded that "there's no mechanism" by

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testimony in response to that incoherent question to imply that she believes that biological plausibility needs to be established with certainty to satisfy Bradford Hill.

57 (DiFeo Br. at 12.)

58 (*Id.* at 13 (emphasis added) (quoting DiFeo Rep. at 29).)

59 (*Id.* (quoting DiFeo Rep. at 16-17).)

which talc could cause or contribute to ovarian cancer.[60] She similarly testified that other scientific articles concluded that talc had no biological effect on tissue.[61] Dr. DiFeo's testimony regarding other researchers' conclusions cannot possibly support plaintiffs' argument that Dr. DiFeo applied a certainty standard of biological plausibility.

Finally, plaintiffs cite portions of Dr. DiFeo's testimony rejecting plaintiffs' theory of migration, but these opinions do not run afoul of the biological plausibility standard either. For example, Dr. DiFeo explained that the biological plausibility studies cited by plaintiffs' experts "'***do not conclusively show***'" that talc can migrate to the ovaries.[62] And while she has opined that talc "has not been shown" to migrate or induce malignant transformation, she elaborated that this was because "[t]he studies on which plaintiffs' experts rely have been performed on flawed cell lines, [and] use physiologically irrelevant concentrations of talc. . . ." [63]

In short, the testimony cited by plaintiffs does not suggest that Drs. Permuth or DiFeo imposed a "heightened standard" or an "incorrect . . . standard" for biological plausibility, much less that they "insist[ed] on certainty or near

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60 (*Id.* at 14 (quoting Dep. of Analisa DiFeo ("DiFeo Dep.") 74:1-19, June 28, 2024 (DiFeo Br. Ex. 2)).)

61 (*Id.* at 15-16 (quoting DiFeo Dep. at 221).)

62 (*See id.* (quoting DiFeo Rep. at 28).)

63 (*See id.* (quoting DiFeo Rep. at 29).)

certainty."[64] Rather, they merely explained that the opinions of plaintiffs' experts are nothing more than bare "hypothes[es]" that are unsupported by scientific data demonstrating that particulate matter applied to the perineum can travel to the ovaries and fallopian tubes or that talc can cause inflammation in the ovaries. These are reliable opinions that apply the proper standard for biological plausibility.

III. PLAINTIFFS' OTHER ARGUMENTS REGARDING DR. BOYD'S OPINIONS ARE ALSO MERITLESS.

Plaintiffs launch a number of scattershot attacks on Dr. Boyd's opinions in the hopes of salvaging their own experts' opinions, which he criticizes. None of their arguments has any merit.

A. Dr. Boyd's Opinions Are Properly Based On His Experience And Review Of The Literature.

Plaintiffs' primary argument is that Dr. Boyd should not be allowed to testify about the flaws in the scientific studies on which plaintiffs' experts rely because he did not conduct additional research to rebut the conclusions or methodologies of those papers. This argument is once again based on a fundamental misconception regarding the role of a defense expert.

First, plaintiffs claim that Dr. Boyd's criticism of Dr. Saed's dose "is

64 (*Id.* at 17-18; Permuth Br. at 16.)

unsupported by any research or methodology"[65] because he did not undertake research to determine what a proper dose would have been. Not so. Even a cursory review of Dr. Boyd's report shows that he is not opining on what the correct ***dose*** would be, but rather that Dr. Saed failed to follow scientifically sound ***principles*** in deciding which dose to use.[66] It is obviously not Dr. Boyd's responsibility to construct a reliable experiment for Dr. Saed's team. And as Dr. Boyd explains, there was "essential information . . . missing" from Dr. Saed's description of the dose he used for his 2019 study, "including how many ml (or µl) were applied to the cells, how many cells were treated, and in what size tissue culture plate or petri dish the treatment took place," making it "impossible to determine the dose of talcum powder (or control) that was used to treat an unknown number of cells" and "rendering the entire experiment uninterpretable from the perspective of cell dosing."[67] While Dr. Saed corrected at least some of those flaws in his 2021 poster, that study "likewise omit[ted] information (such as a description of the number of cells that were treated over a given surface area)," which is "needed to ascertain the talcum powder dosage for the experiments,"

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65 (*See id.* at 5-7.)

66 (*See* Boyd Rep. at 6.)

67 (*Id.*)

again "rendering any results impossible to interpret."[68]

These sorts of criticisms fall well within the proper role of a defense expert. *See, e.g.*, *In re Abilify*, 299 F. Supp. 3d at 1368 (it is appropriate for defendants to offer "essentially, critiques of [p]laintiffs' experts' evidence, methodologies, and conclusions"); *Feliciano*, 2020 U.S. Dist. LEXIS 199069, at *8 (defense experts may simply "pok[e] holes in [other side's] argument"). And Dr. Boyd is not alone in raising these methodological concerns; peer reviewers have echoed these criticisms, expressing significant concerns as to whether Dr. Saed's experiments are based on a sound methodology, including due to his failure to justify the dose used.[69]

In any event, Dr. Boyd did explain how Dr. Saed should have gone about determining a proper dose even if he did not provide a specific concentration or quantity that should have been used. As Dr. Boyd explained in testimony that plaintiffs tellingly omit from their brief, "whenever you're exposing cells in vitro to a xenobiotic, whatever it may be, the accepted scientific methodology is to begin with the lowest dose possible, working up to the point where a biological effect is observed . . . rather than starting with a toxic dose that literally kills all the cells in the Petri dish and then working backwards to a dose that doesn't seem to kill the

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68 (*Id.* at 11.)

69 (*See id.* at 6 (quoting peer reviewers' concerns).)

cells."[70]

Nor is there any merit to plaintiffs' argument that "Dr. Boyd's opinions related to the dosing used by Dr. Saed run in contrast to the opinions of Defendants' other experts or to the previous holdings of Chief Judge Wolfson."[71] Judge Wolfson did not remotely suggest Dr. Saed could not be criticized. In fact, she excluded his testimony related to cancer causation and genetic mutations, which are the subjects of the most recent publications on which plaintiffs' experts rely.[72] And while she admitted Dr. Saed's testimony related to oxidative stress, she acknowledged that the flaws in Dr. Saed's methodology raised "serious questions . . . which a jury will have to weigh." *In re Johnson & Johnson*, 509 F. Supp. 3d at 146. In other words, she anticipated that both sides would present expert witness testimony on these issues and the jury would weigh these issues. While defendants believe that Judge Wolfson did not fully appreciate her gatekeeping role (which has since been clarified in amended Rule 702), she never contemplated that Dr. Saed's work would not be criticized trial and any suggestion to that effect by plaintiffs misrepresents her ruling. In fact, Judge Wolfson denied

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70 (Boyd Dep. 97:5-22 (cited in Boyd Br. at 6).)

71 (Boyd Br. at 6.)

72 Plaintiffs' experts now use the results of his studies for precisely that purpose. (*See* Defs.' Mot. to Exclude Ops. Related to Biological Plausibility/Mechanism, ECF 33013-1, at 33.)

a similar motion in finding that another defense expert, Dr. Benjamin Neel, could "reliably" rebut "Dr. Saed's opinion." *In re Johnson & Johnson*, 509 F. Supp. 3d at 196.

Nor did Dr. Mossman endorse Dr. Saed's opinion. Plaintiffs claim that Dr. Mossman "testified that the doses by Dr. Saed were 'appropriate.'" (Pls.' Br. at 7.) She did nothing of the sort. Instead, she testified that the doses she used in a different study a decade prior had been proper.[73] Plaintiffs do not offer any evidence that the doses Dr. Mossman used are similar to those used by Dr. Saed and his colleagues. In any event, the fact that a dose might be appropriate for one purpose does not mean it is appropriate for another, and certainly does not mean it is appropriate to support the inference plaintiffs' experts seek to draw from Dr. Saed's work—that it is biologically plausible for talc, at the doses to which the plaintiffs have been exposed, to cause human cancer.

Second, plaintiffs' argument that Dr. Boyd cannot criticize Dr. Saed's use of a cell transformation assay kit because he has "never used a commercial assay kit"

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[73] (*See* Dep. of Brooke Mossman 353:3-359:9, Apr. 8, 2019 (Ex. 31 to Davidson Decl.) (cited in Boyd Br. 7 & n.4) (discussing Shukla, *Alterations in Gene Expression in Human Mesothelial Cells Correlate with Mineral Pathogenicity*, 41(1) Am. J. Respiratory, Cell & Molecular Bio. 113 (2009)).) Judge Wolfson characterized the testimony similarly, *see In re Johnson & Johnson*, 509 F. Supp. 3d at 142-43, but that appears to be a mistake. The cited portion of Dr. Mossman's deposition does not talk about Dr. Saed's work at all.

is similarly misplaced.[74] Dr. Boyd does not opine that the use of a kit in and of itself is problematic, but that the kit cannot possibly show ***malignant*** transformation. As he explained at his deposition, the problem is that Dr. Saed and his colleagues conflate the concept of cell transformation, in the sense of changes to the cell that allow it to grow differently in vitro, with malignant transformation, which renders the cells capable of forming cancerous tumors.[75] Again, Dr. Boyd's critique is consistent with those of several peer reviewers, who rejected his research in part because the assay was insufficient to show malignant (cancerous) or even neoplastic (tumor-like) transformation.[76]

Instead, as Dr. Boyd explained in his deposition, "in order to show that . . . the treatment of cultured cells in a Petri dish have . . . rendered [them] malignant, it's ultimately necessary to put those cells into an animal, generally in a subcutaneous context . . . to show [that] they're creating tumors in animals." Here,

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74 (Boyd Br. at 7-8.)

75 (*See* Boyd Dep. 122:2-6.)

76 (*See, e.g.*, SAED_SEPT222021_SUPPL_000101 ("SAED" documents attached collectively as Ex. 32 to Davidson Decl.) (peer reviewer identifying the "use of a single in vitro soft agar assay to claim malignant transformation" as a "critical fatal flaw[]" in Dr. Saed's study and recommending that "[a]ll claims for 'malignant transformation' should be changed to 'cell transformation'"); SAED_SEPT222021_SUPPL_000069 (Gynecologic Oncology reviewer later finding that "the reliance on a single commercial assay for assessment of transformation that has not been established in the literature" was among "several major issues" with the 2020 experiments and "[o]f primary concern").)

too, several peer reviewers agreed with Dr. Boyd.[77] Dr. Boyd's decades of experience as a molecular biologist and researcher, as well as a reviewer for the very types of journals that rejected Dr. Saed's research, is a more than sufficient basis to explain these principles of cancer biology, regardless of whether he has used the same assay as Dr. Saed's laboratory.[78]

Third, plaintiffs' perfunctory argument that Dr. Boyd should be prohibited from criticizing Dr. Saed's use of "ovarian surface epithelial ovarian cells rather than fallopian tube cells" is likewise meritless. Once again, Dr. Boyd's view is shared by peer reviewers, one of whom called a study of ovarian epithelial cells "of limited relevance" to ovarian cancer.[79] Plaintiffs' argument chiefly takes issue with the fact that Dr. Boyd has not done his own research with fallopian tube cells and could not pass a memory test at his deposition asking him to cite studies on fallopian tube cells.[80] But nowhere do plaintiffs explain why Dr. Boyd would need

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77 (Boyd Dep. 118:15-119:14; SAED_SEPT222021_SUPPL_000101 ("to clearly show that these cells were malignant, an in vivo experiment such as subcutaneous injection of these transformed cells into an immune compromised mouse model, would need to be conducted showing tumor growth and ability to invade neighboring tissue").)

78 Indeed, it makes no sense to criticize Dr. Boyd for never having used a particular assay kit, when the entire thrust of his testimony is that the assay is not particularly informative.

79 (SAED_SEPT222-21_SUPPL_000069.)

80 (Boyd Br. at 8-9 (citing Boyd Dep. 134:4-10, 136:22-25, 137:4-13).)

to conduct such research himself to point out that "scientists now agree that most high-grade serous ovarian cancers originate in the fallopian tubes."

Finally, plaintiffs fault Dr. Boyd for not reviewing some of the literature Dr. Levy looked at in forming his opinions.[81] But they fail to explain how the five studies they claim Dr. Boyd did not review are relevant to his criticisms of Dr. Levy's report.[82] Notably, Dr. Boyd's criticisms largely relate to specific opinions and statements in Dr. Levy's report in which he misinterpreted or incorrectly represented the findings of other studies[83] or are criticisms of claims for which Dr. Levy provides "no citations or data" at all.[84]

In short, Dr. Boyd's opinions regarding the methodologies underlying the literature on which plaintiffs' experts rely are properly based on a review of that literature (and other literature), alongside his experience as a researcher, professor and peer reviewer.

B. Dr. Boyd's Testimony Highlighting The Flaws In Studies Will Assist The Trier Of Fact.

Plaintiffs also argue that Dr. Boyd should be precluded from testifying about the flaws in published literature, including Dr. Saed's work, as well as two

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81 (Boyd Br. at 9-10.) Apparently, plaintiffs mean that these articles were on Dr. Levy's reliance list but not Dr. Boyd's.

82 (*Id.*)

83 (*See, e.g.*, Boyd Rep. at 23.)

84 (*Id.* at 22-23.)

macrophage studies,[85] because the methodologies underlying these papers "have already been reviewed, scrutinized, and published" by peer reviewers, and allowing Dr. Boyd to explain their flaws "would imply that Dr. Boyd has more authority that could lead juries to give his opinions greater weight."[86] This is an odd argument coming from plaintiffs, whose experts attack every scientific paper addressing cohort studies that has been published in the peer-reviewed scientific literature. It is also utterly meritless.

It is axiomatic that "publication (or lack thereof) in a peer reviewed journal . . . [is] a relevant, though ***not dispositive*** consideration" of reliability. *Goodrich v. John Crane, Inc.*, No. 17-9, 2018 WL 4677773, at *23 (E.D. Va. Sept. 28, 2018) (emphasis added) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592-94 (1993)) (rejecting argument that "criticisms of the 2000 Hodgson and Darnton study are unfounded" since "the study has been peer reviewed"); *see also Meyers v. Arcudi*, 947 F. Supp. 581, 587 (D. Conn. 1996) ("[E]ven if a theory or technique is subject to publication and peer-review, it does not necessarily follow that it is scientifically valid."); *In re Zantac*, 644 F. Supp. 3d at 1171-73

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85 Mandarino, *The Effect of Talc Particles on Phagocytes in Co-Culture with Ovarian Cancer Cells*, 180 Environ. Res. 108676 (2020) (Ex. 33 to Davidson Decl.) and Emi, *Transcriptomic and Epigenomic Effects of Insoluble Particles on J774 Macrophages*, 16(10) Epigenetics 1053 (2021) (Ex. 34 to Davidson Decl.).

86 (Boyd Br. at 17-19.)

("acceptance in the scientific community and peer review are not necessarily sufficient to establish the reliability of a scientific methodology"). Indeed, as explained in greater detail in Defendants' Opposition to the Motion to Exclude the Opinions of Dr. John Kornak ("Kornak Br."), the scope of pre-publication review is frequently narrow, and "it is a serious error . . . to assume that just because an article is accepted for publication, even in a prestigious scientific journal,[87] the science it contains is therefore valid." *Valentine v. Pioneer Chlor Alkali Co.*, 921 F. Supp. 666, 675 (D. Nev. 1996).

Critiques of peer-reviewed studies are thus routine and unobjectionable aspects of expert testimony. *See, e.g.*, *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d at 418-19 & n.14 (permitting defense expert to opine that a peer-reviewed study "suffer[ed] 'from multiple methodological and analytical flaws that render its conclusions inaccurate'") (citation omitted); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Pracs. & Prods. Liab. Litig.*, No. 09-02100, 2011 WL 6302573, at *14 (S.D. Ill. Dec. 16, 2011) (permitting expert to "critique flaws in [published epidemiological] studies" in light of his experience). (*See also* Defs.' Mem. of Law in Opp'n to PSC's Mot. to Exclude Ops. of Dr. John Kornak at 13-16 (collecting additional cases).)

[87] The obscure journals that have accepted Dr. Saed's work are decidedly not "prestigious."

In any event, plaintiffs' acknowledgment that "peer reviewers are typically experts in the field" only highlights why Dr. Boyd's opinions are not just admissible but correct, since his views are largely shared by several peer reviewers of journals that harshly rejected Dr. Saed's work, before it was ultimately accepted by a bottom-of-the-barrel journal.[88] *See In re Johnson & Johnson*, 509 F. Supp 3d at 137 (citing criticism from peer reviewers as one reason to limit Dr. Saed's testimony). As Dr. Boyd notes in his report, "the manuscript corresponding to Dr. Saed's 2020 abstract/poster was ***repeatedly rejected*** when Dr. Saed submitted it to ***multiple*** journals for publication," as was the manuscript accompanying his 2021 poster.[89] And although Dr. Saed did eventually succeed in having the manuscript published with "some alterations" in an "obscure" and "second-tier" journal, he did not address several of the comments from peer reviewers from the more prestigious journals who found Dr. Saed's methods and research extremely troubling.[90] Accordingly, this argument, too, should be rejected.

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88 (Boyd Br. at 18-19.)

89 (Boyd Rep. at 5, 13-14 (emphasis added).)

90 (*Id.* at 14-16.)

C. Dr. Boyd Did Not Engage In "Cherry-Picking."

Plaintiffs also claim that Dr. Boyd's opinions are unreliable because he cherry-picked evidence that supports his position.[91] Plaintiffs are correct as a legal matter that an expert opinion may be deemed unreliable if it fails "to adequately account for contrary evidence." *In re Onglyza (Saxagliptin) & Kombiglyze (Saxagliptin & Metformin) Prods. Liab. Litig.*, 93 F.4th 339, 345 (6th Cir. 2024) (citation omitted). But their claim that Dr. Boyd ignored contrary evidence is ridiculous. Plaintiffs do not point to any study that Dr. Boyd failed to consider. To the contrary, they point to passages in his deposition where Dr. Boyd ***testified that he "read"*** three studies—a recent epidemiological study by O'Brien, a report from Health Canada, and an abstract published by the International Agency for Research on Cancer ("IARC").[92] Their argument is that Dr. Boyd also testified that he believed "reviewing" a paper requires more in-depth analysis than "reading" it. Thus, they infer that because he used the word "read" with respect to these three papers, he must have given them short shrift.

Plaintiffs' effort to read between the lines of Dr. Boyd's testimony should be rejected. Dr. Boyd specifically testified that he "gave considerations" to the

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[91] Plaintiffs also accuse Drs. Permuth and DiFeo of "cherry-picking" but only in the sense that they purportedly do not account for the potential presence of asbestos impurities in talc. That is discussed, *supra*.

[92] (Boyd Br. at 15.)

O'Brien paper.[93] He further explained that he did not focus on it more because it is an epidemiology paper and he is "not an epidemiologist."[94] Likewise, Dr. Boyd "g[a]ve . . . consideration" to the Health Canda report, but ultimately did not credit it because he felt it "contradict[ed it]self with respect to the weight of the epidemiological data."[95] Experts may be required to account for all relevant evidence, but they certainly are not required to agree with it all. Finally, the IARC abstract was published in July. Dr. Boyd has "considered the findings,"[96] though obviously could not have included it in a report served in May. In any event, the abstract, which was published in advance of a forthcoming monograph, is less than two pages long and rehashes already-existing evidence. It is entirely reasonable for Dr. Boyd to "strongly disagree" with its conclusions. Disagreement is not cherry-picking.

D. Dr. Boyd Is Qualified To Testify About The Design And Methodologies Of In Vitro Studies.

Finally, plaintiffs briefly argue that Dr. Boyd is not qualified to testify about "the design, objectives, methodology, and other aspects of in vitro studies" because he has "spent a large part of his career in clinical settings," and "it has been over

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93 (Boyd Dep. 144:25.)

94 (*Id.* 143:23-24.)

95 (*Id.* 147:23-24, 149:4-12.)

96 (*Id.* 152:23-153:1.)

twenty years since [he] was in a research lab."[97] This argument, too, should be rejected.

As noted above, Dr. Boyd is the director of the Institute of Cancer Research at the Feinstein Institutes for Medical Research, a professor in the Department of Obstetrics and Gynecology and Department of Pathology and Laboratory Medicine at the Zucker School of Medicine at Hofstra/Northwell and has over three decades of experience conducting cancer research.[98] In that time, Dr. Boyd has both conducted a wealth of his own research and served as a "peer reviewer" "[m]any times" of research articles like those plaintiffs' experts rely upon.[99] Indeed, Dr. Boyd has "authored or coauthored more than 200 articles, reviews, book chapters and editorials on the molecular and genetic bases of gynecologic or breast cancers," has been "invited to present more than 150 lectures on th[o]se topics throughout the world" and has "served as a peer reviewer in many capacities, including as a standing member of scientific review groups of the NIH, the Department of Defense cancer research program, and the American Cancer Society."[100] Moreover, Dr. Boyd has served on editorial boards of journals

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97 (Boyd Br. at 19-20.)

98 (*See* Boyd Rep. at 1; *see also* Boyd CV.)

99 (Boyd Dep. 71:24-72:1.)

100 (Boyd Rep. at 2; *see also* Boyd CV at 32 (listing 45 journals where Dr. Boyd has served as an ad hoc reviewer).)

"[m]any times," including Gynecologic Oncology, the Journal of Clinical Oncology, Anticancer Research, and the American Journal of Pathology.[101] To say that Dr. Boyd lacks the qualifications to review and criticize the studies plaintiffs' experts rely upon here strains credulity.

Plaintiffs mostly sidestep this breadth of experience, suggesting that Dr. Boyd's work is immaterial since "it has been over twenty years since Dr. Boyd was in a research lab."[102] But that claim is, at best, misleading. While Dr. Boyd did testify that the "last time [he] was ***physically*** in a lab conducting research" was probably 20 years ago (Boyd Dep. 49:23-50:3 (emphasis added) (cited in Boyd Br. at 19)), plaintiffs leave out the very next answer in Dr. Boyd's testimony in which he explains that he has "an active laboratory-based research program" where he "participate[s] in laboratory research programs in terms of collaboration," even though he does not have a "personal research laboratory" at this point of his career.[103] Indeed, as Dr. Boyd's CV illustrates, he has been a co-author on a dozen different peer-reviewed articles over the last decade relating to cancer research, assuaging any concerns that Dr. Boyd's experience in research is as ancient as

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101 (Boyd Dep. 72:2-4; *see also* Boyd CV at 7.)

102 (Boyd Br. at 19.)

103 (Boyd Dep. 50:4-9.)

plaintiffs suggest.[104]

In short, Dr. Boyd's decades of experience, education and training as a researcher, professor, peer reviewer and scientist, especially as it relates to cancer research, more than qualify him to testify about ovarian cancer studies.

CONCLUSION

For the foregoing reasons, the Court should deny plaintiffs' motions to exclude portions of the opinions of Drs. Permuth, DiFeo, and Boyd.[105]

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Respectfully submitted,

/s/ Susan M. Sharko
Susan M. Sharko
FAEGRE DRINKER BIDDLE & REATH LLP

Allison M. Brown
Jessica Davidson
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP

Attorneys for Defendants Johnson & Johnson and LLT Management, LLC

104 (*See* Boyd CV at 33, 45-46.)

105 Section VI of plaintiffs' motion against Dr. DiFeo is moot because Dr. DiFeo is not offering case-specific opinions.